

Estimated burden per response to comply with this mandatory collection request: 4 hours. **Submission** of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

IF YOU ARE LOCATED IN:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN. SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 605324352

Br 2

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, **DELAWARE**, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, **VIRGIN ISLANDS**, OR WEST VIRGINIA. SEND APPLICATIONS TO:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, **OKLAHOMA**, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING. SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 KYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 760114005

03034932
X

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS

1 THIS IS AN APPLICATION FOR (Check appropriate item)

- A NEW LICENSE
- B AMENDMENT TO LICENSE NUMBER
- C RENEWAL OF LICENSE NUMBER

2 NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

DR ALI MOOSVI
1640 RT 88 SUITE 201
BRICK NJ 08724

3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Stable Cardiology Consultants LLC.
1640 RT 88 SUITE 201
BRICK NJ 08724

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

732-840-6801

TELEPHONE NUMBER

2009 FEB 25 AM 10:37
RECEIVED REGION 1

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9 FACILITIES AND EQUIPMENT

10 RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY AMOUNT ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

ALI R. MOOSVI, M.D.

Ali Moosvi

2/6/2009

FOR NRC USE ONLY

TYPE OF FEE FEE LOG FEE CATEGORY AMOUNT RECEIVED CHECK NUMBER COMMENTS

APPROVED BY

DATE

143418

Renewal for Radioactive Materials License

Applicant

Shore Cardiology Consultants LLC.
1640 Rt. 88 Suite 201,
Brick, NJ 08724

RE: NRC Renewal of Materials License. Application # 29-30497-01

Application content items 5-11

5. Radioactive Material
6. Purpose for which licensed material will be used
7. Individuals responsible for Radiation Safety Program and their Training Experience
8. Training for individuals working in or frequenting restricted areas
9. Facilities and equipment
10. Radiation safety program
11. Waste Management

5= Any byproduct material identified in 10 CFR 35.200

6. Any cardiac imaging and localization procedure approved in 10 CFR 35.2000

7. The radiation safety officer for this license is Ali R. Moosvi, MD

8. The following will be instituted but not limited to: 10 CFR Part 20.1101(c) and regulatory guide 10.8 (Task FC 415-4), Appendix A which refer to 10 CFR 19.12 and 35.21

See attachment 8A for a detailed list of our Radioactive materials staff Training

9. Radioactive Materials shall only be used at Shore Cardiology Consultants 1640 Rt. 88 Suite 201 Brick NJ

10. Radioactive material listed in conditions 5 shall be used under the supervision of Ali R. Moosvi, MD/ RSO

RADIOACTIVE MATERIALS STAFF TRAINING

10 CFR Part 20.1101(c) and Regulatory Guide 10.8 (Task FC 415-4), Appendix A which refers to 10 CFR 19.12 and 35.21 specifies that personnel must be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

It is further stated that it may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training must be provided for all workers.

Specific individuals who will receive training at this site include:

- 4 Radiation Safety Officer
- Technologists
- Ancillary personnel who might work in restricted areas on an occasional basis (Custodian, security personnel, attendants, reception staff)
- Ancillary personnel who work with patients who have received radiopharmaceuticals
- Personnel who might have concerns regarding the presence of radioactive materials at the facility. (Management, secretarial staff)

Training will occur prior to any person entering a restricted area and/or during **new** employee orientation.

Training will be provided upon initial employment, and whenever potentially significant **new** procedures or concerns became evident, and at least annually.

The training program will, at the least, inform personnel of management's commitment to ALARA, provide an overview of the radioactive materials program at this facility, provide information on the biological effects of radiation and its relative risk in the workplace, and provide instruction in safety measures to follow to minimize exposure.

Whenever training is conducted, the training topics covered, the individuals in attendance, the date of the training, and the instructor will be recorded and training records will be maintained in the department until released for disposal by the regulatory agency.

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
FOR THE POSSESSION AND USE OF NATURALLY-OCCURRING AND
ACCELERATOR-PRODUCED MATERIAL

Documentation of Attachments to this Application

Section Attachment Description Items 5-11

5. Radioactive Materials Requested in This Application
 - 5(a)Element and Mass number
 - 5(b)Chemical and/or physical form
 - 5(c)Maximum amount that will be possessed at any on time

6. Purpose(s) for which licensed material will be used

7. Individual(s) responsible for Radiation Safety Program, their training experience and e-mail address(s)

8. Training for individuals working in or frequenting restricted areas

9. Facilities and Equipment

10. Radiation Safety Program

11. Waste Management

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #5

A.

B.

C.

Radioactive Materials Requested in this Application

Radiopharmaceuticals

The applicant wishes to receive a license for all radiopharmaceuticals allowed under 10 CFR 35.200. These radiopharmaceuticals, to be used in an out-patient facility, will be limited to:

Radioisotope	Form	Amount (mCi) of each form	Item 6: Purpose of use
$^{99m}\text{Tc}^*$	Pertechnetate	80.00	Human use
	HSA	40.00	Human use
	f-YP	40.00	Human use
	Other FDA-approved forms	200.00	Human use
$^{201}\text{Tl}^*$	Chloride	60.00	Human use
$^{99m}\text{Tc}^*$	Pertechnetate	50.00	Quality Control and Calibration
$^{201}\text{Tl}^*$	Chloride	1.00	Quality Control and Calibration

Sealed Sources for Quality Control and Calibration as described on the next page.

These sealed sources are authorized under 10 CFR 35.57.

Note: The sources of radiopharmaceuticals will be obtained from the radiopharmaceutical supplier in unit dose form. The applicant will not obtain a generator for ^{99m}Tc , or make "kits" using the radiopharmaceuticals listed in this application (the "supplier" includes the radiopharmacy).

All unused sources, contaminated syringes, etc., that are obtained from the radiopharmacy will be returned to the radiopharmacy for disposal. Only those materials originating or used in the facility (wipes, etc.) will be kept in the facility for Decay-In-Storage (DIS).

It is recognized that the ^{201}Tl and ^{57}Co are licensed by the "State," including Agreement States.

Sealed Sources

The sealed sources will be obtained from

Technology Imaging Services
8433 South Avenue, Building 4
Suite 1
Poland, OH 44514

The sources used for the dose calibrator are

Element	Mass Number	Form	Max., mCi	Catalog #
Ba	133	sealed	0.250	NES-353
Cs	137	sealed	0.200	NES-356
Co	57	sealed	5.000	NES-206

The sources used for the gamma camera are:

Element	Mass Number	Form	Max., mCi	Catalog #
Co	57	sealed	7.500	NES-391

A description of the sources provided by the supplier is given below. If the sources decay to levels below those stated in 10 CFR 35.50(b)(1)(2) they will be replaced.

Isotope Calibrator Reference Sources

For checking calibrator accuracy, performance and consistency. Good practice dictates, and regulatory agencies recommend, that isotope calibrators used for measuring diagnostic and therapeutic doses of radiopharmaceuticals be checked regularly over the calibrator's range of measurements. Calibrator performance is easily monitored by using the following calibrated standards to verify the accuracy of its assays:

- A long-lived source, such as ^{137}Cs ($T_{1/2} = 30$ years!), to avoid the tedium of constant decay corrections.
- A ^{57}Co Source ($T_{1/2} = 270$ days) that simulates $^{99\text{m}}\text{Tc}$, the most common radionuclide in nuclear medicine.

By keeping a daily log of the values obtained on selected ranges with both standards, the user develops a performance record that detects calibrator error or failure before a mistake is made in a patient's dose.

Both sources are supplied in a 20% epoxy in a 27ml plastic vial, 85 mm H x 30 mm D. Calibrated to $\pm 1\%$.

063-562 Calibrated ^{133}Ba Source, 250 μCi
 101-356 Calibrated ^{137}Cs Source, 200 μCi
 063-261 Calibrated Simulated $^{99\text{m}}\text{Tc}$ Source (^{57}Co alt!), 5mCi

^{57}Co Cobalt Flood Sources

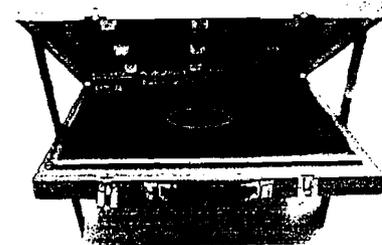
Intended Uses:

- Daily intrinsic uniformity checks
- Extrinsic collimator checks
- Linearity and resolution checks with bar phantom
- As transmission sources
- Quality control for accreditation and regulatory requirements

The sources contain ^{57}Co , uniformly dispersed and sealed in a rigid plastic lucite casting. Each source is supplied in an attractive cushioned, lead-lined, plastic storage case, reducing the exposure rate at surface to approximately 1.4mR/hr.

All sources are inspected for emission non-uniformity less than $\pm 1\%$ at 2 standard deviation and verified statistically. Each source is supplied with a Leak-Test certificate.

Flood Source: 062-297 18" ϕ diameter, 5mCi



Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #6

APPLICATION FOR MATERIAL LICENSE

5 (a) Any radiopharmaceutical identified in 10 CFR 35.200

5 (b) Any radiopharmaceutical identified in 10 CFR 35.200 except generators and gas

5 (c) Maximum amount that will be possessed at any one time- As needed

6. Purpose(s) for which licensed material will be used-

This license application is only for nuclear cardiology procedures implemented in a private practice facility. The materials used will be obtained from a licensed supplier of Radiopharmaceuticals. The applicant will not obtain a $^{99m}\text{Tc}/^{99}\text{Mo}$ generator. There is no intent to purchase any materials in "bulk" form, and all radiopharmaceuticals will be obtained in unit-dose form from the radiopharmacy.

Some radioactive wastes from the radiopharmacy (i.e., unused unit-doses or syringes containing radioactivity) will be returned to the radiopharmacy for disposal. Records of this transfer will be maintained by the applicant. Other wastes, such as used syringes, tubings, sponges, wipes or other contaminated materials, will be held by the applicant in storage for Decay-In-Storage (DIS). These materials may have an associated bio-hazard which makes them non-returnable to the radiopharmacy. The facility design will meet state regulatory limits, for exposure limits for the radiation worker and general public

The applicant will NOT be using ^{131}I -sodium iodide in any quantity, radioactive gases, radioactive aerosols, or conducting any radionuclide therapy procedures, and is therefore exempt from the Quality Management program requirement. We will not establish a Quality Management program under this license.

If the needs of the applicant-physician requires the operational scope to change, the application will be amended before the applicant-physician implements such changes.

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #7

#7 Dr. Ali Moosvi is currently the acting RSO for SCC. His credentials for this position meet and exceed the minimum standards set forth by the NRC. Attached are copies of his Radioactive Training Program for your review. His email address is ticker786@aol.com.

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

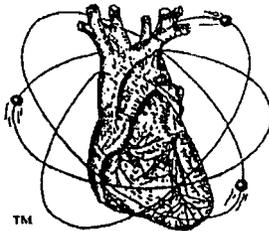
*This document is to attest that
Ali R. Moosvi, MD, FACC, FACP*

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

*and has provided evidence of attendance in this program and evidence
of achieving the objectives of this program through examination.*

This program provides the following levels of accomplishment:



- 50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35 and Agreement States)
- 5 Continuing Education Units (CEU)
- 50 Technical/Professional Credit specified by the
American Pharmaceutical Association and the
American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

21 October 1998

Date Class Commenced

Charles H. Rose

Authorized Signature

1973536

Affidavit of Competency

Institute for Nuclear Medical Education

5660 Airport Blvd., Suite 101, Boulder, Colorado 80301 — 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

NUCLEAR MEDICAL EDUCATION PROGRAM

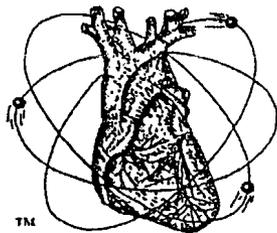
Affidavit of Academic Completion and Competency

*This document is to attest that
Ali R. Moosvi, MD, FACC, FACP*

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

*and has provided evidence of attendance in this program and evidence
of achieving the objectives of this program through examination.
This program provides the following levels of accomplishment:*



- 50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35 and Agreement States)
- 5 Continuing Education Units (CEU)
- 50 Technical/Professional Credit specified by the
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21 October 1998

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CA-1

STIONS

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New Jersey Office of the Attorney General
Division of Consumer Affairs**

**THIS IS TO CERTIFY THAT THE
Board of Medical Examiners**

HAS REGISTERED

**ALI R. MOOSVI
1640 RT 88
SUITE 201
BRICK NJ 08724-7724**

FOR PRACTICE IN NEW JERSEY AS A(N): Medical Doctor

**04/27/2007 TO 06/30/2009
VALID**



Signature of Licensee/Registrant/Certificate Holder

25MA05586800

LICENSE/REGISTRATION/CERTIFICATION #



ACTING DIRECTOR

PLEASE DETACH HERE
IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:

Board of Medical Examiners
P.O. Box 183
Trenton, NJ 08625

PLEASE DETACH HERE

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #8

Personnel Qualifications and Training

Technologist Qualifications

All nuclear medical technologists will be registered or certified in nuclear medicine by the ARRT, CNMT, or ASCP, or they will, if allowed by local or state laws, have the equivalent training in nuclear medicine. If local or state laws require registration/certification and a state license, then the applicant will comply with those laws.

In addition to the above, the physician applicant will interview the technologist, obtain a resume of his/her experience, and evaluate the technologist through close observation of her/his nuclear medical techniques in actual operation.

Personnel Training Program

Who will be instructed:

All personnel (professional/technical and ancillary) will be instructed. The professional/technical personnel will include, but not be limited to: technologists, authorized users, physicists, and physicians who are not authorized users, but may be present when by-product material is being used. The ancillary personnel include nursing, clerical, housekeeping, and other personnel who may frequent the area where material is being used.

Instruction Frequency:

Personnel will be instructed before assuming duties within the vicinity of radioactive materials during an annual refresher training program and whenever there is a significant change in the duties, regulations, or terms of the license. There will also be instruction as deemed necessary by the RSO for all personnel after spills, misadministrations, and other incidents including monitored high personnel exposure.

Topics of Instruction:

Instruction will include, but not be limited to, the following subjects:

- A. Applicable regulations, license conditions and workers' rights
- B. Areas where radioactive materials are used or stored
- C. Potential hazards associated with radioactive materials and bio-hazards, and procedures for each area where employees or physician staff work
- D. Appropriate radiation safety procedures
- E. Licensees' in-hours work rules
- F. Each individual's obligation to report unsafe conditions to the RSO
- G. Appropriate responses to emergencies or unsafe conditions
- H. Correct operation and use of radiation detection equipment

Personnel who work with the materials will also receive copies of procedures for the following: monitoring the performance of imaging equipment, ordering and receiving radioactive material, opening packages, recording by-product material use, surveying radiation areas, safely using radiopharmaceuticals, disposing of waste and responding to emergencies.

Method of Instruction:

Instruction will be formal, didactic, and/or individual, as needed. It will include, but not be limited to: personnel monitoring programs, ALARA, rules for safe use of radiopharmaceuticals, emergency procedures, floor plans showing areas of use and storage, and a tour of the facility.

Method of Evaluation:

The RSO or her/his agent will evaluate and informally observe the individual's work activities.

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #9

Facilities—Radiation Safety Equipment

Vial Shields • Optional*

This lead shield, available in either 0.5" or 0.25" thickness, was designed to permit safe, convenient handling of vials containing liquid radionuclides. It is particularly important when milking "cows." The vial provided with the generator may be placed in the shield, and the generator eluted in accordance with the manufacturer's instructions.

The shield has a high density lead-glass panel, with shielding thickness equivalent to that of the lead wall, so that the entire process may be viewed. The shield has a screw-type cover with an opening through which a syringe needle may be inserted for withdrawal of the radionuclide from the vial.

*Vial shields will not routinely be maintained unless the license or amendments allow the preparation of radiopharmaceutical kits and/or possession and use of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ Generators.

Lead Lined Storage Container

For Contaminated Syringes

- Safely holds used hot syringes
- Rapid, safe disposal



Specifications:

Lead Shielding:	1/8" Lead Shielding
Measures:	6 3/4" high 5" diameter
Weight:	7 lbs.

Pro-Tec@ Syringe Shield

Pro-Tec Syringe Shields are the first functional, safe, unobtrusive, easy to use, unbreakable, and light-weight syringe shields available. The slimline design is comfortable for both patient and clinician. The patented spring loaded twist lock of the stainless steel and brass screw lock keep disposable syringes snug inside the shield. Pro-Tec Syringe Shields are half the weight of other syringe shields, yet the Pro-Tec will normally reduce exposure from $^{99\text{m}}\text{Tc}$ by a factor of 20. The Pro-Tec Vu-Thru has a viewing port, so that drawing and injecting can be accomplished with the syringe in the shield. A special optical glass window with a density of 2.3 gm/cc covers the port.

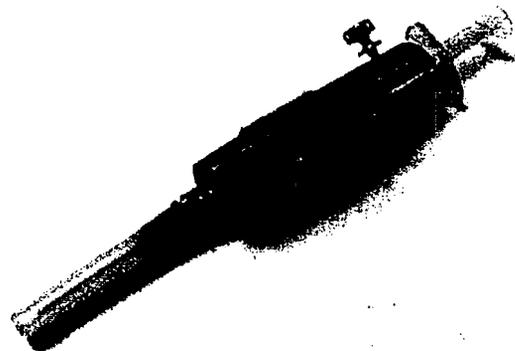


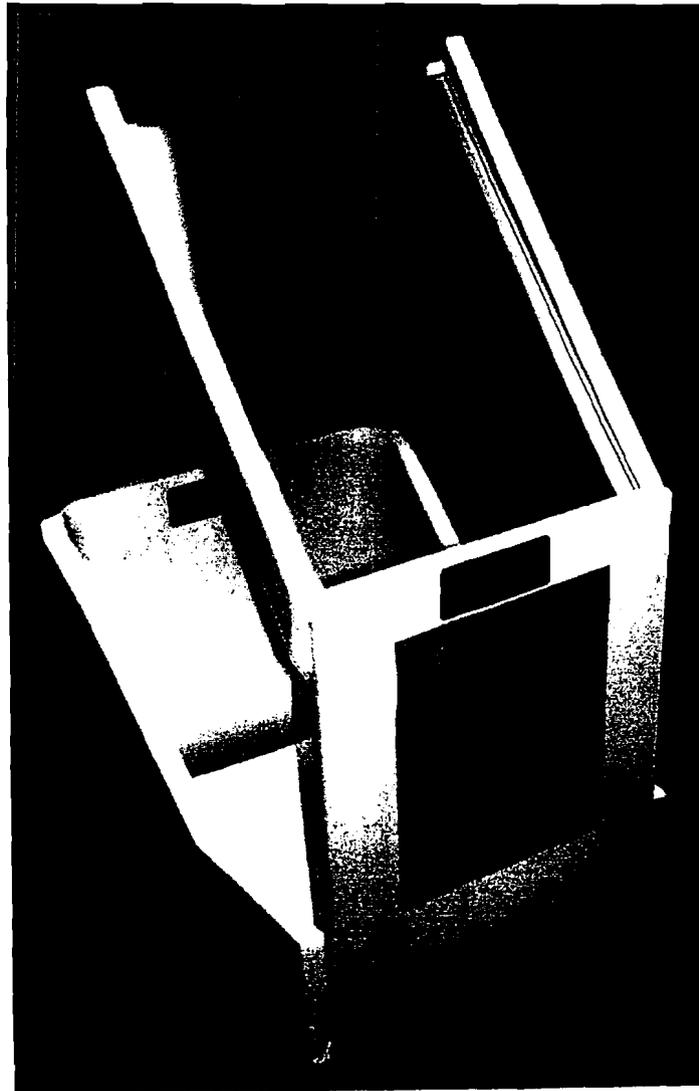
Table Top Barrier Shield

Protect head and body from radiation when working with radioactive materials.

The shield most suited to your work load. Provides exceptional protection to the clinician when setting up technetium generators, filling syringes, etc.

1/2" thick wall protects the torso while the base provides ample working surface and balance against tipping. Face shielding is optically clear 1/4" thick lead glass, cantilevered for unimpaired viewing of work area. The lead equivalent of the glass is 2.00mm.

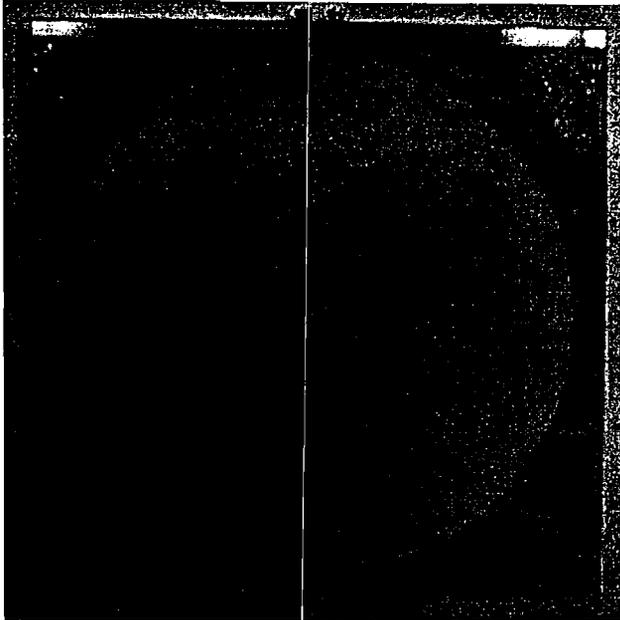
Unit can be moved with little effort to any convenient location, allowing total flexibility in choice of work area.



Equipment Quality Control Phantoms

See also "Notes on Sealed Sources" on page K 2 of this application.

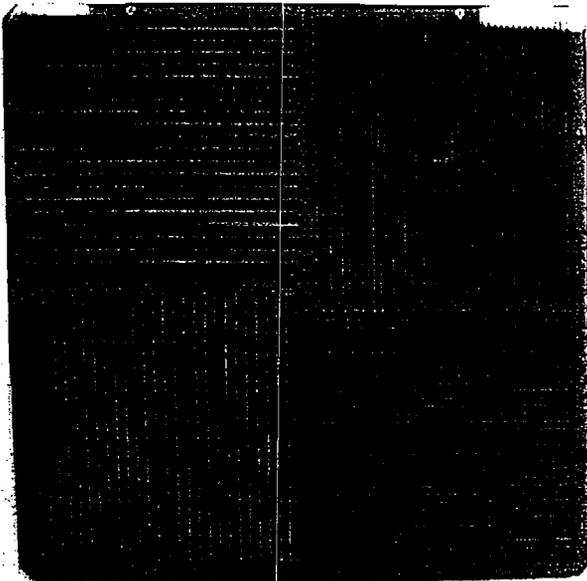
Extra Large Flood Phantom Source



Emission Phantom

Extra Large Flood Phantom Source

- 15" diameter pool completely includes a patient's lungs, allowing accurate patient position when using a diverging collimator
- 16.5" x 16.5" x 1" thick, with 15" diameter x 0.5" cavity for suitable radionuclide.
- Easy to fill—drain ports provided.



Transmission Phantom

Standard High Resolution Bar Phantom

Bar Widths: 1/4", 3/16", 5/32", 1/8" (6.4 mm, 4.8 mm, 4.0 mm, 3.2 mm)

- 15" field across bar configuration (38 cm)

Quality Control Procedures for Gamma Cameras

I. It is crucial to practice routine quality control for the gamma camera. Your quality control program may vary from the one below due to individual equipment problems, but a basic routine program should include the following daily quality control activities. All records of your program must be retained for two years.

1. **Collimator:** The camera should be evaluated extrinsically with the collimator on the detector. The same collimator should always be used for proper reproducibility.
2. **Pulse Height Analyzer:** The Pulse Height Analyzer (PHA) should be adjusted according to the manufacturer's instructions. The PHA must be rechecked with the actual gamma spectrum emitted from the patient before you perform procedures. Any change in line voltage, ambient room temperature, or camera high voltage will change the PHA adjustment, so the PHA should be checked under these conditions.
3. **Flood Field Uniformity:** Obtain a flood field uniformity image with the standard collimator on the detector. The flood field phantom or source should be placed on the collimator before obtaining an image (The acquisition should be for pre-set counts. Record the total number of counts and the acquisition time.) Flood field uniformity should be **checked** daily.

NOTE. Evaluate the image for uniformity errors, and determine specific uniformity performance, if you note any uniformity problems.

II. The following additional quality control activity should be performed at least once a week. Quality control records must be retained for two (2) years.

1. **Resolution-Distortion:** A four-quadrant resolution bar phantom should be placed diagonally to the X- and Y-axis directly on the collimator, and the flood field phantom (or flood field source) placed on the bar phantom. Obtain an image with a clinical PHA window or 20-30% and a total of 0.5 million-1.0 million counts (the acquisition should be for pre-set counts. Record the total number of counts and the acquisition time.)

NOTE. The resolution-distortion image will reveal changes in resolution-distortion or significant uniformity changes. This procedure is clinically important because these factors will effect your study analysis. The uniformity flood image will only provide information on uniformity. Resolution imaging must be performed weekly because uniformity will appear satisfactory in the presence of deteriorating resolution.

Frequency of Tests

Uniformity

Daily

Resolution-Distortion

Weekly

Pulse-Height Analysis

As used

III. Other quality control procedures may be performed at monthly or quarterly intervals. These procedures include, but are not limited to.

1. **Background Flood:** A flood field done without a flood source, to determine noise, background electronic noise, and other factors affecting image quality. Obtain an image with the collimator on the detector for a preset time of at least 20 minutes. The PHA setting should be 30%. Do not increase the image intensity. Record the time, counts, and image evaluation.
2. **Check of Maximum Count Rate Capacity:** With the detector directed horizontally into the room and the collimator removed, set a 20-30% clinical window. Turn on the machine to display the received count rate. Place a syringe, containing a patient dose of 5-20 mCi of ^{99m}Tc in a syringe shield. Bring the syringe toward the detector with the long axis of the shield directed at the detector. The count rate will increase to the maximum count rate, and then maintain ("saturate") or decrease ("paralyze").

- IV The following quality control procedures must be performed at least annually. You may need to perform some them more frequently, as your results indicate
- 1 **Crystal, Detector, Resolution** Determine the detector resolution using a small point dry source of ^{99m}Tc or ^{57}Co . The activity should not exceed $50\mu\text{Ci}$. The procedure should be performed intrinsically with the collimator off the detector (intrinsic). The actual procedure will depend on the electronics available and the operator's techniques
If the resolution (expressed in % full width half max) has changed by 50-80% from the anticipated value you may need to examine the detector quality, PHA calibration, or measurement technique.
 - 2 **Count Rate Linearity and 20% Count Rate Loss Determination:** This should be performed if changes appear in the detector efficiency, shifts in the detector resolution, changes in dynamic procedure accuracy, or increased count rates in clinical studies caused by changes in techniques or radiopharmaceutical agents. Follow each procedure's protocol to make these determinations.
- V From time to time, the system's operating conditions may warrant additional system performance studies. Studies may include point sensitivity, linearity, and an entire imaging chain analysis, including the computer, ECG gate, and other accessories.
- VI **Safety Checks.** All "safety checks" must be performed at least quarterly. They may be performed more often as indicated by manufacturer's alerts.

Dose Calibrator Accuracy Test

Licensee: _____
 License Number: _____ Amendment: _____ Date: _____
 Dose Calibrator Manufacturer: _____ Model: _____ Serial#: _____

Source Data

Radioisotope: _____ Activity: _____ Model: _____ Serial: _____

Assay Data

A. _____ Calibration Date: _____
 B. _____ Decay Factor: _____
 C. _____ Decay Corrected Activity: _____
 Average: _____ Dose Calibrator Setting: _____ Calculated Deviation: _____

Source Data

Radioisotope: _____ Activity: _____ Model: _____ Serial: _____

Assay Data

A. _____ Calibration Date: _____
 B. _____ Decay Factor: _____
 C. _____ Decay Corrected Activity: _____
 Average: _____ Dose Calibrator Setting: _____ Calculated Deviation: _____

Source Data

Radioisotope _____ Activity: _____ Model: _____ Serial: _____

Assay Data

A _____ Calibration Date: _____
 B. _____ Decay Factor: _____
 C _____ Decay Corrected Activity: _____
 Average. _____ Dose Calibrator Setting: _____ Calculated Deviation: _____

Evaluation _____

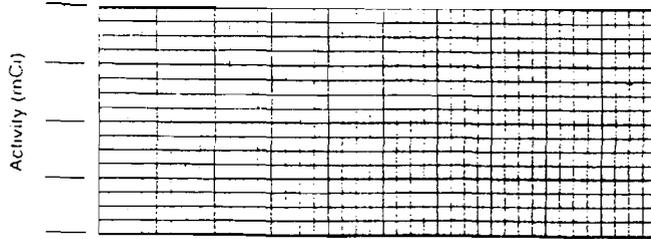
Signed(Performed By): _____ Date: _____

Signed(Confirmation): _____ Date: _____

Dose Calibrator Geometry Test

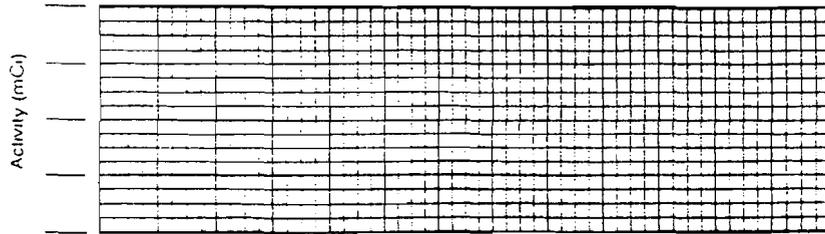
Licensee: _____
 License Number: _____ Amendment: _____
 Date: _____ Radionuclide: _____ Activity: _____ Volume: _____
 Dose Calibrator Manufacturer: _____ Model: _____ Serial#: _____

Syringe Geometry Dependence Syringe Size: _____ ml



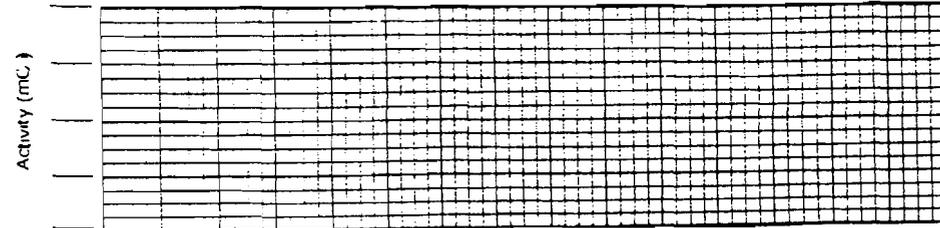
Milliliters _____
 Correction Factor _____

Syringe Geometry Dependence Syringe Size: _____ ml



Milliliters _____
 Correction Factor _____

Vial Geometry Dependence Vial Size _____ ml



Milliliters _____
 Correction Factor _____

Analysis of Geometry Dependence Data From Above: _____

Signed(RSO) _____ Date: _____

Dose Calibrator Geometry Test Form

Constancy Check with ^{57}Co NBS Source

This decay table can be used to correct the decay of the ^{57}Co source for the correction of the activity for Q.C. on the Dose Calibrator

DECAY TABLE FOR "COBALT

Time, (t), in Days	$e^{-0.69315 / \text{halflife} * t}$
	0.997453
2	0.994913
3	0.992379
4	0.989851
5	0.987330
6	0.984815
7	0.982307
8	0.979805
9	0.977309
10	0.974820
11	0.972337
12	0.969861
13	0.967391
14	0.964927
28	0.931084
29	0.928712
30	0.926347
31	0.923987
365	0.394226
730	0.155414
1095	0.061268
1460	0.024154

Calibration And Quality Control of The Dose Calibrator

The following procedures will be followed in performing calibration and quality control procedures on the dose calibrator. These may be performed at more frequent intervals as determined by the RSO.

Geometry Dependence

Frequency

At time of installation and following repair or replacement of the chamber or relocation of the device.

Acceptable Range

±5% with the types of containers used by the application.

- a) Using a syringe of the type used for routine procedures, draw up 1-10 mCi of $^{99m}\text{TcO}_4$ in 0.5cc volume.
- b) "Count" the syringe in the dose calibrator in the same way that patient doses are measured.
- c) Draw an additional 0.5 cc's of water into the syringe and count as in b).
- d) Repeat the procedure until there is no less than 2.0 cc's in the syringe.
- e) Select the volume closest to that normally used for patients as the "standard" and divide the millicuries indicated by each of the other volumes into the standards to determine the volume correction factors.
- f) If any of the correction factors are greater than 1.05 or less than 0.95 **make a correction** table for the calibrator showing indicated activity at that volume vs. true activity at that volume.

Accuracy

Frequency

At time of installation and not less than annually thereafter as well as after repair, adjustment or relocation.

Acceptable Range

±5% of the expected activity

- a) Use the calibrated reference sources of ^{57}Co , ^{133}Ba , and ^{137}Cs as authorized under this license for this procedure (see "sealed sources").
- b) "Count" each source at its correct setting on the calibrator, subtract the measure of background on that setting, and record the activity. Repeat this procedure for three measurements of each of the sources.
- c) Average the three readings, of each source, and divide into certified activity of the source after corrected for decay.
- d) The results of the calculations, section c) must fall within the range of 1.05 and 0.95 (to fit within +/-5%). If it does not fall within this range, consider repair or recalibration. However, if it exceeds 1.10 and .90 (+/-10% range) repair, recalibration or replacement must be made.

Linearity

Frequency

At time of installation and not less than quarterly thereafter, as well as after repair, adjustment, or relocation.

Acceptable Range

±5% of the expected activity

- a) Obtain a syringe containing not less than 20 mCi of ^{99m}Tc from the radiopharmacy.
- b) "Count" the syringe in the dose calibrator at the earliest time in the morning, i.e., 8:00 a.m., and record the mCi indicated, minus background.
- c) "Count" the syringe again not less than six times during a 78 hour period of time (3.25 days). Record the readings, minus background.
- d) Plot the values obtained on semilog graph paper and draw the best-fit line through the values. Draw a second line through the expected points as calculated using decay factors of the expired time.
- e) Calculate the maximum deviation of the observed line from the calculated line. If the deviation is more than ±5% (0.05) the instrument will be adjusted or repaired. If it can not be adjusted or repaired, a correction table or graph that will allow conversion from activity indicated to true activity will be made and placed on the calibrator.

The activity to be equal to not less than the maximum amount ever obtained from a supplier and counted to 10% Ci by decay.

On a quarterly basis, the applicant will determine that the measurement chamber is in place and that the instrument is zeroed according to the manufacturer's instruction.

Constancy

Frequency

Once prior to use on each day of use as well as after repair, adjustment or relocation

Acceptable Range

±5% of the anticipated value.

- a) Measure the ^{57}Co sealed, dose calibrator source on the ^{201}Tl , ^{57}Co , and ^{99m}Tc settings. Measure the ^{137}Co source similarly if deemed necessary by the RSO.
- b) Record the background at the same settings.
- c) Determine the activity indicated, at the settings, by subtracting the background, b), from the readings determined in a), and record this value.
- d) Compare the measured ^{57}Co activity to activity calculated from a ^{57}Co decay table or graph
- e) Determine action levels for the reading at each setting reflecting the range of ±5% of the anticipated reading. If the value is greater than ±5%, notify the RSO and if it is 10% or greater from the expected value, the instrument will be repaired or replaced.
- f) Record above constancy measurement.

CARDIO-WIPE II

A scaler/timer system interfaced to a NaI crystal detector. The scaler/timer features a built-in power supply with full-range control from zero to 2000 volts. Separate lighted switches are provided for on-off line frequency test, count, stop, and reset functions. A single MHV connector is provided on the back panel, along with a line fuse holder. The NaI (TI) well scintillation probe is mounted in a base which provides 1.9" cm of virgin lead shielding to all externally exposed surfaces. The 4.5 x 5.1 cm crystal contains a well 3.8 cm deep and 1.7 cm in diameter. The well is lined with 0.25 mm aluminum. A single MHV cable connector is provided for interface.

Model WP-2000 Well Scintillation Probe (For Test Tube Samples)

Scintillator: 1.75" (4.5 cm) x 2" (5.1 cm) NaI (TI) well crystal; well: 0.7" (17 mm) diameter x 1.5" (3.8 cm) deep; well entrance window: 0.1 inch aluminum (0.25 mm)

PM Tube: 2" (5.1 cm) diameter

Resolution: 9% or better full-width-half-maximum for ^{137}Cs (0.662 MeV)

Shielding: 0.75" (1.9 cm) virgin lead surrounds crystal

Dimensions: 10.75" (27.3 cm) Height x 6" (15.2 cm) Base Diameter:
4" (10.2 cm) Lead Height / 4" (10.2 cm) Lead Diameter

Connectors: High Voltage Cable: MHV / Signal Cable: BNC

Note with AA-2010 System, only one cable is required for both high voltage and signal; single MHV

Technical Data Model 500 Scaler/Timer

Readout: 999.999 counts, all electronic, no mechanical register

Resolving Time: Better than one microsecond

Input Sensitivity: 0.25 volt negative

Voltage: 0—2000 volts, continuously variable, zener regulated; coarse and fine controls

Preset Timing: 0.5, 1, 2, 5, 10 minutes and manual; derived from power line frequency, accurate to 0.03%

Power Requirement: 105—125 volts, 60 Hz (230 volts, 50 Hz)

Detector Input: MHV connector

Shipping Weight: 14 pounds

Dimensions: 4.5" (11.4 cm) high x 11" (27.9 cm) wide x 10.5" (26.7 cm) deep

In Line Fuse: 1 amp

Manufacturer of origin is The Nucleus 761 Emory Valley Road, Oak Ridge, TN 37830-2561.

CARDIO-WIPE II—Technical Specifications

The following empirical data was obtained in a controlled bench-top environment to determine the Minimum Detectable Activity (MDA) and Lower Limit of Detection (LLD) of the system, as required by 32 Ill. Adm. Code 335.2080. The instrument was operated without pulse height analysis. An NIST traceable ^{57}Co source was used to approximate the response of the system to $^{99\text{m}}\text{Tc}$. Calculations were performed using the method described in the Appendix to Regulatory Guide 4.14 Revision 1, of the Nuclear Regulatory Commission. Because the system will be used to perform analysis of wipe and swipe samples, no correction factors were used for variations in sample volume or fractional radiochemical yield.

Raw Data

Average Background: 390 cpm, 6.5 cps

Standard Deviation of Background: 20 cpm, 2.5 cps

^{57}Co NIST Standard Source: Serial Number C-113-3

0.69 μCi (1,528,572 dpm) on Date of Testing

Net Yield in Well: 1,050,610 cpm

Calculations

System Efficiency

$1,050,610\text{cpm} \div 1,528,572\text{dpm} = 0.68\text{cpm/dpm} = 68\%\text{ efficient}$

Lower Limit of Detection for $^{99\text{m}}\text{Tc}$

$(4.66 \times 2.5) / (3.7 \times 10^4) \times (0.68 \times e^{-0.693/6h \times 1h}) = 0.0005\mu\text{Ci} (1144\text{ dpm})$

This instrument meets the requirements of 10 CFR 35 to detect 2000 disintegrations per minute

PROCEDURE FOR CALIBRATION OF THE SURVEY INSTRUMENT

The applicant will not calibrate the survey instrument, but will have a contractor perform the calibration on an annual basis, or after any repair other than the replacement of batteries. The procedure for obtaining this calibration is outlined below:

- 1) The selected contractor will have an NRC or Agreement State License to perform calibrations, and this license will be documented by the applicant prior to contracting this service. It is anticipated that the calibration will be performed either by the manufacturer of the instrument, or by Syncor Pharmacy, 1313 Washington Ave., Golden, CO 80401, (303) 279-1914.
 - 2) If a contractor remote from the location of the facility is used, either a replacement survey meter will be obtained during the calibration, or the facility will not operate during the time the system is not present. The replacement meter will match the performance of the original meter.
 - 3) The Check Source will be read and documented at the time of calibration.
 - 4) Upon receipt of the instrument from calibration, the applicant will check its apparent rate of exposure with built-in or independent check source (license exempt), and note the level of exposure on the survey meter. Prior to each operation, the instrument will be checked to determine that the reading is still the same, indicating the instrument is still calibrated.
 - 5) The report of survey meter calibration, obtained from the contractor after calibration, will include (but not limited to) the following information:
 - Identification of who did the calibration
 - The calibrator's license number
 - Identification of the instrument's owner
 - Description of instrument, including:
 - Manufacturer
 - Model number
 - Serial number
 - Type of detector
 - A description of the calibration source and its exposure rate on a specific date
 - The calibration procedure
 - For each calibration, note:
 - Calculated exposure rate
 - Indicated exposure rate
 - Deduced correction factor
 - Scale selected
 - Reading indicated by the battery-check
 - Angle between the flux field and detector
 - Position of the detector and its shield
 - Apparent exposure rate from the check source
- (Continues)

Calibration And Quality Control of The Dose calibrator

Geometry Dependence — Vials

To test the geometry dependence for 30 cc glass vial, draw up 1.0 cc of the $^{99m}\text{TcO}_4$ solution into a syringe and inject it into the vial. Assay the vial, and record the volume and millicuries indicated.

Remove the vial from the calibrator, and using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water. Assay again, and record the volume and millicuries indicated.

Repeat the process until you have assayed a 19.0 cc volume. The entire process must be completed within ten minutes.

Select the volume closest to that normally used for for mixing radiopharmaceutical kits as a standard value. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. You may also graph the data and draw horizontal 5% error lines above and below the chosen "standard volume."

If any of the correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model and serial number of the calibrator. The Radiation Safety Officer (RSO) will sign this form (see attachment. H5)

Calibration And Quality Control of The Dose calibrator

Geometry Dependence — Vials

To test the geometry dependence for 30 cc glass vial, draw up 1.0 cc of the $^{99m}\text{TcO}_4$ solution into a syringe and inject it into the vial. Assay the vial, and record the volume and millicuries indicated.

Remove the vial from the calibrator, and using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water. Assay again, and record the volume and millicuries indicated.

Repeat the process until you have assayed a 19.0 cc volume. The entire process must be completed within ten minutes.

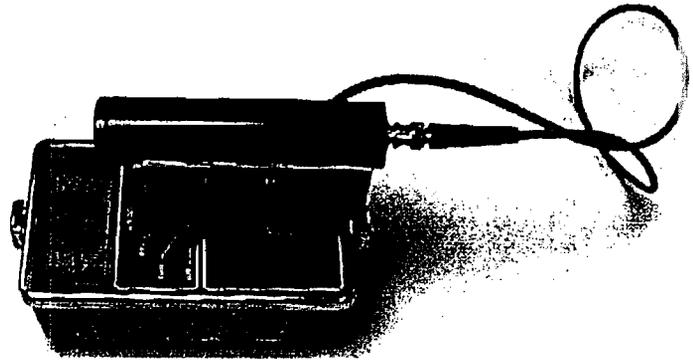
Select the volume closest to that normally used for mixing radiopharmaceutical kits as a standard value. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. You may also graph the data and draw horizontal 5% error lines above and below the chosen "standard volume."

If any of the correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model and serial number of the calibrator. The Radiation Safety Officer (RSO) will sign this form (see attachment H5)

Surveyor 2000™ Portable Survey Meter

Model: SWGM

- Rugged Housing
- Sliding Beta Shield
- Solid Internal Connectors
- Energy Compensated
- Beta and Gamma Sensitivity



RADIATION DETECTED: Alpha, beta, gamma with external probe, gamma and x-ray with internal detector.

DETECTOR: GM tube, internal. Choice of GM probes, external.

RANGE: 0-2000 mR/h in 5 linear ranges. 0-240,000 cpm.

HIGH VOLTAGE: Electronically stabilized, factory set at 900 V.

HV TEST: Exclusive self test to verify detector HV power supply.

CONNECTOR: MHV

ACCURACY: Within 10% of reading for ^{137}Cs when calibrated according to NRC Reg. Guide 10.8.

ENERGY RESPONSE: $\pm 20\%$ from 40 KeV to 1.2 MeV (internal detector).

WARM-UP TIME: None.

SATURATION: Typically > 1000 R / hr for most GM probes (provided by exclusive anti-saturation circuit). More than 5R / h for pancake GM probes.

RESPONSE TIME: Switch-selectable optimized for each range. 0-90% of final reading as follows:

Range	Fast	Slow
X0.1	6 seconds	25 seconds
X1	2 seconds	6 seconds
X10	1 second	3 seconds
X100	< 1 second	1 second
X1000	< 1 second	1 second

DEAD TIME COMPENSATION: Exclusive circuitry provides near linear response.

BATTERY COMPLEMENT: Single 9-volt (MN 1604 or equal). The additional battery holder may be used as storage of spare or parallel-wired.

BATTERY LIFE: More than 100 hours, or over 200 hours with parallel option.

TEMPERATURE: Operational from -40°C to $+60^{\circ}\text{C}$.

HUMIDITY: Less than 5% change in reading from 10-95% RH.

CONTROL: Eight-position rotary switch as indicated.

DISPLAY: Ruggedized, recessed, high-torque 1mA meter with 3.35" (8.51 cm) scale marked 0-2 mR/h, 0-2400 cpm, 'Bat. ok,' 'HV ok.' Meter protected by impact-resistant Lexan® polycarbonate window.

GEOTROPISM: Within $\pm 2\%$ of full scale.

SHOCK: 100g per lightweight machine of MIL-STD 202C, method 202B.

VIBRATION: 5g in each of three mutually orthogonal axes at one or more frequencies, from 10-33Hz.

AUDIO: A built-in speaker, with panel mounted on/off switch, provides audible "click" for each detector pulse.

With the speaker off, an audible alarm sounds (if desired) when meter is over full scale on any range.

CONSTRUCTION: Splash-proof, shock proof, two-piece all metal case. Scratch-resistant laminated control panel and Bicon Kleen-Krome® trim on case top, and durable black polyurethane paint on handle and case bottom.

SIZE: 4.25 x 8 x 6.8" including handle and probe clip (10.8 x 20.3 x 17.3 cm)

WEIGHT: 2.2 lbs (1 kg), excluding probe.

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #10

Procedure for Spills

The following procedures for major* and minor' spills will be followed in our facility. These procedures will be posted, in larger form, and used in the employee training program, as indicated in that section.

NOTICE

SPILL PROCEDURE

MINOR SPILLS

1. Notify all persons in the area that a spill has occurred.
2. Prevent the spread of the contamination by covering the spill area with absorbent paper and secure the area.
3. Survey all personnel in the area to assure they are not contaminated. If contamination is present, decontaminate.
4. With the RSO or another person not involved in the spill do the monitoring with the GM survey meter, determine the margins of the contaminated area for decontamination.
5. Clean up the spill using disposable gloves, foot coverings if indicated, and absorbent paper. Remove the paper covering the area, clean side out, avoiding contamination, and place in a plastic bag for transfer to the radioactive waste container. Clean the area, decontaminate, and place all wipes, papers, and gloves in the bag for transfer to the waste container.
6. After decontamination, survey the area with the GM survey meter. Included in the survey the area around the spill area, Check your hands, clothing, and shoes for contamination.
7. Complete the "Radioactive Spill Report" and "Radioactive Spill Contamination Survey."
8. With the RSO, evaluate measures to be taken to prevent such spills.

MAJOR SPILLS

1. Clear the area by notifying all persons in the room that a spill has occurred by use caution that no individual who is contaminated will leave the area.
2. Prevent the spread of the contamination by covering the spill area with absorbent paper and secure the area.
3. Confine the movement of potentially contaminated personnel to an area, in the same room, where they can be monitored and decontaminated. Be sure that they don't spread the contamination. Survey these people and, if not contaminated, have them leave the area.
4. If practical, without spreading the contamination, shield the spill but don't allow the spread of contamination or increase your exposure.
5. Close the room and lock, or otherwise secure the area, to prevent entry. Post a notice on the door indicating that entry is prohibited.
6. Notify the Radiation Safety Officer (RSO).
7. Follow the direction of the RSO for decontamination of the area, complete required documentation and evaluation of the incident.

Personnel Decontamination Suggestions (First Steps)

- a) Remove contaminated clothing and store it for evaluation and decay
- b) Flush the skin with tepid water, wash with mild soap and dry with absorbent paper. Repeat this step as required as long as at least 15% of the counts are removed with each washing. Avoid contamination from the wash water and use as little water as practical.
- c) Radioactive material in the eyes should be flushed with water, or eye wash, and an eye cup.

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1000 SIGNS-5011000000

* The applicant considers a "major" spill to be a release of more than 50 mCi of ^{99m}Tc, or more than 25 mCi of ²⁰¹Tl. A major spill may also be defined as one in which a potential exposure rate of more than 10 mrem per hour could occur. Sealed sources, being solid material, cannot spill. If sealed sources could spill, values for a spill considered "major" would be adjusted upward.

Procedure for Area Surveys

Ambient Exposure Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be surveyed at the end of each day.
- 2) Areas that are used for only radiopharmaceutical waste storage, where there are no daily activities, will be surveyed at the end of each week.
- 3) The above survey information will be recorded on the "Ambient Exposure Survey" report form (see next page), and the RSO will be notified if unexpectedly high (2X normal background) or low levels are found. Prompt notification is particularly important where radionuclides should not be present, or levels exceed established values.
- 4) Surveys will be completed as part of the "spill" procedure.

Removable Contamination Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be wipe tested at the end of each week that the materials are used.
- 2) Areas that are used for only radiopharmaceutical waste storage, where no daily activities take place, will be wipe tested at the end of each week.
- 3) The above survey information will be recorded on the "Contamination Survey Record" report form (see page three). The RSO will be notified if removable contamination greater than 2000 dpm/100cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl is found. Also notify the RSO if 100dpm/100cm² of any other radioisotope is found, or if any removable contamination is found in a unrestricted area. The assay must be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl. The assay must also be able to detect 200 dpm/100cm² of any other radioisotope. This assay will use the absolute counting technique outlined in the "Contamination Survey Record." The survey will use "swipes," as indicated on the third page of this section.
- 4) Removable contamination surveys will be completed as part of the "spill" procedure.

CONTAMINATION ACTION LEVELS: (DPM/100 CM² OF SURFACE CONTAMINATION)

Area	Contaminant Radionuclide
	⁵⁷ Co, ^{99m} Tc, ²⁰¹ Tl
Unrestricted Areas or Uncontrolled Areas	2,000

Decontamination Procedures

I. General Rules

- A. Contain the contamination—never allow uncontaminated areas to be contaminated in the clean-up process.
- B. Avoid any activity release from the restricted area by immediately isolating the suspected area. It is acceptable to "overreact" to the spill by initially isolating an area significantly larger than the initial spill site.
- C. Address personnel contamination before decontaminating the facility.
- D. Obtain others' help to monitor and carry out decontamination procedures and other activities.
- E. Always follow the license conditions and establish protocols for spills, surveys, and documentation.

II. Personnel Decontamination

- A. If physical injury requires medical attention, administer care immediately. Keep in mind that contamination may be present.
- B. Decontaminate eyes by washing them with the eye wash solution from the "Decontamination Kit". Wash eyes over a sink and allow the water to flush down the drain.
- C. Remove all contaminated garments, i.e., laboratory coat, gloves, etc., and step onto an uncontaminated surface to monitor residual activity.
- D. Use the following decontamination techniques for skin decontamination. Take great care not to spread the contamination to clean surfaces during these procedures. Decontaminate in a sink, and allow the water to flush down the drain.
 1. Flush the surface with *tepid* water, and remonitor for removal/residual activity.
 2. Wash with NUC-WASH I and rinse with tepid water. Remonitor for removal/residual activity.
 3. Wash with NUC-WASH II and NUC-WASH III, if necessary. With each wash, rinse with tepid water and remonitor for removal/residual activity.
 4. If NUC-WASH III is used, and residual activity exists, use a soft brush on the skin. **AVOID BREAKING OR IRRITATING THE SKIN.**
 5. If residual activity persists after all decontamination steps are completed, and if the RSC agrees that additional decontaminations are not warranted or practical, then ensure that the contaminated area is not further spread and contaminated materials are not ingested. Adding moisture to the skin may allow contaminated skin to release more activity after a few hours. At that time, washing the skin again may be helpful. If hands are contaminated, cotton gloves may absorb moisture containing activity and prevent contamination from spreading.
 6. Determine the value of performing Bio-Assays on the individual for any ingested or inhaled activity. These Bio-Assay techniques include, but are not limited to: nose wipes, saliva samples, and/or after a few hours, blood and/or urine samples. If any Bio-Assay samples are obtained, the personnel exposure records must show the nature of the samples, and the numerical results of their analysis.
 7. Complete all required records, including the appropriate spill, personnel exposure, ingestion, or incident reports.

(continues on Attachment M5B)

Decontamination Procedures (continued from M5A)

III. Surface Decontamination

- A. Avoid all unnecessary exposure of personnel during decontamination, and never allow uncontaminated areas to become contaminated during these procedures.
- B. Consider using radioactive decay as a decontamination technique if the activity can be isolated and secured.
- C. Wear booties, gloves, a laboratory coat and, if possible, an apron, or other materials that will allow easy removal of contaminated articles.
- D. Cover all "wet" areas with absorbent papers.
- E. Monitor the area suspected of contamination, and identify its outer limits with a marker or barrier.
- F. Place absorbent pads adjacent to the area to prevent exposure to decontamination personnel.
- G. Decontaminate the outer margins of the area with the appropriate NUC CONTAM Solution (A, B, and/or C,) working inward toward the major area of the spill.
 - 1. Use a minimum amount of solution and water.
 - 2. Clean successively smaller areas.
 - 3. Use tongs; don't touch the wipes or decontamination materials.
 - 4. Place all contaminated materials in plastic bags for Decay in Storage (DIS).
 - 5. After decontamination, place absorbent paper over the "clean" area to avoid contact with residual activity.
 - 6. When all areas are decontaminated and released, they must be swipe tested for residual activity.
 - 7. Complete all required spill reports and records and document the decontamination.

Procedure for Ordering Radioactive Materials

We will follow the procedures below when ordering radioactive materials.

1. The RSO or a designee must authorize each order for radioactive materials. Each ordered material must be authorized under the license. The amount ordered must not exceed the possession limits under that license.
2. A record of all orders will be maintained. The record should show the isotope, activity, for and supplier of the radioactive material (see the "Radioactive Material Package Order and Receipt Record.")
3. Radioactive materials will only be received during normal working hours. The materials will be delivered directly to the nuclear medical area and placed on the table by the nuclear medical technologist or RSO, as indicated on the floorplan. If the technologist or RSO are not present when the material is delivered, the reception staff will follow the procedures listed below. The procedures will also be posted in both the reception office and the nuclear medical room.
4. The technologist or RSO will check to ensure that the package contains the ordered material.
5. The technologist or RSO will then follow the "Procedures for Safely Opening Packages Containing Radioactive Material."

NOTICE

Receipt of Packages Containing Radioactive Materials

When Packages containing radioactive materials are delivered, have the carrier agent wait in the reception area and call the nuclear technologist or the Radiation Safety Officer.

If the nuclear technologist or the Radiation Safety Officer are not available, then follow the following instruction:

1. Have the carrier place the package on a cart or wheelchair.
2. If the package is damaged or shows signs of being wet or having been wet, immediately contact one of the individuals listed below and:
 - Demand that the carrier's agent, the delivery person, remain at the facility to be monitored to determine that neither this person nor the vehicle is contaminated and,
 - Do not touch the package or allow others to touch the package but remove it, on the cart or wheelchair, to a secure area, i.e., the nuclear medicine room, where it will be examined by the RSO or other authorized personnel.
3. If the package is not damaged and shows no signs of being wet:
 - Sign the receipt and retain a copy.
 - Transport the package to the nuclear medicine area on the cart or wheelchair and:
 - Place the package at the location marked: "Radiopharmaceutical Receipt Area," and secure (lock) the room.

Note to cleaning, security, and other personnel: If packages should be delivered during non-working hours but while you are present, you are **NOT** authorized to make a receipt, and the package must be refused. The carrier's agent may not leave the package. The package must be refused. The carrier's agent may not leave the package at the facility during non-working hours. If you have any questions, contact the individual listed below:

Radiation Safety Officer: _____

Nuclear Medical Technologist: _____

Procedure for Safely Opening Packages Containing Radioactive Material

Procedure for safely opening packages:

- 1) Wear rubber or latex gloves to prevent hand contamination.
- 2) Visually inspect the package for any sign of damage, such as wetness, physical damage, stains, etc., and if any is noted, immediately notify the RSO.
- 3) Measure the exposure rate from the package with a GM type survey meter (side window) at 1 meter, and then at the surface. If the exposure rate is higher than expected, stop and notify the RSO for specific instructions before proceeding. (Exceptions: See 20.1906)

Note: The maximum surface exposure rate of labeled packages is: White 1-0.5 mR/hr, Yellow 1-50 mR/hr, and Yellow 111-200 mR/hr. None of these rates should be exceeded. (DOT 49 CFR 172)

- 4) Wipe an area of 300 square cm to evaluate the possible presence of removable contamination. Measure wipes using a sodium iodide true detector to insure dpm do not exceed regulatory limit. (See 5f2)
- 5) If the initial surveys are satisfactory, open the package according to the following procedure:
 - a) Remove the packing slip.
 - b) Open the outer package following the supplier's instructions, if instructions are provided.
 - c) Open the inner package and verify that the contents agree with the packing slip.
 - d) Check the integrity of the final source container. Look for broken seals, loss of volume, moisture, or stains on the packing material. If anything is found in a condition other than expected, immediately notify the RSO.
 - e) Remove the source container and place it on an absorbent pad.
 - f) Remove the now empty shipping box to an area with low background exposure, and survey with a sensitive GM survey meter. If the box is contaminated:
 - (1) Treat as radioactive waste and remove for DIS and
 - (2) Wipe the external surface of the final source container and assay the wipe, in a low background area, for any removable radioactivity. Use the procedure for assay of wipes as established in the "Contamination Survey Record" (section III) to determine the sample counts to dpm.
 - (3) Notify the RSO.
 - g) If the shipping box is not contaminated, remove and obliterate the radiation labels before discarding in the in-house trash.
- 6) Recheck the contents of the package to be sure it is the material that was ordered.
- 7) Check the activity of the source in the Dose Calibrator.
- 8) Log the material "in" on the correct Radioisotope Distribution Record.
- 9) Finish the "Radioactive Material Package Order and Receipt Record" as provided on the next page of this section.

DIS — Decay In Storage

dpm — Disintegrations Per Minute

RADIOISOTOPE WASTE DISPOSAL PROCEDURE

Disposal By Transfer

- 1) Spent syringes and unused sources obtained from the radiopharmacy will be returned to the supplier. Only materials from the radiopharmacy will be returned to the supplier. Retain records of all materials returned to the radiopharmacy with the "Unidose Record—Radiopharmacy Radiopharmaceutical Unidose Record" form, located in the Radiopharmaceutical Record section of this application.

Disposal By Decay-In-Storage (DIS)

- 1) Short-lived material, i.e., materials with a physical half-life of less than 65 days, will be disposed of by DIS
- 2) Radioisotopes that are currently active (activities not used nor returned to the radiopharmacy) will be kept in the lead storage container for not less than two half-lives. These will then be transferred to the DIS storage container, as described below, after the radiation label has been violated and shielding removed.
- 3) Syringes and capped needles will be placed in a separate container for eventual disposal (after DIS), in compliance with state and local public health regulations .
- 4) Injection paraphernalia, such as swabs, gauze, tubes, and other contaminated materials, will be placed directly in the DIS containers.
- 5) All materials placed in the DIS container will have the radiation labels violated and the shielding removed. These materials will be placed inside the container, in 2-ply plastic bags. When the bag is full, or every few weeks, the bag will be sealed with string or tape, and identified with the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The bag will then be contained for additional DIS, if required. No material will be disposed in less than 10 half-lives of the longest half-life in the container.
- 6) Prior to disposal , as in-house waste, the bag will be monitored with the following technique:
 - a) GM survey detector will be checked for proper operation
 - b) Bag will be removed to a low-level background area (less than 0.05 mR/hr)
 - c) All surfaces of the bag will be monitored
 - d) If there is no exposure above background, the bag may be discarded. If there is exposure , the bag will be returned to DIS
 - e) Complete records of DIS will be maintained on the "Disposal By Decay In Storage Record " form, located on the next page

Note: Sealed sources, such as ^{57}Co , ^{133}Ba , and ^{137}Cs , that must be disposed of by the applicant, will be disposed of by transfer to a supplier who has a license to receive such material. This transfer will be completely documented by the applicant prior to disposal.

Personnel External Exposure Monitoring Program

Personnel External Exposure Monitoring Program

Our Personnel Exposure Monitoring Program will include, but not be limited to, the following activities:

- 1) The RSO will promptly review all exposure reports and look for workers whose exposure is unexpectedly high or low.
- 2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body film badge. A contract service will process these badges monthly.
- 3) All individuals who handle radioactive material that emits ionizing photons on a regular basis will be issued a TLD finger monitor. A contract service will process these badges monthly.
- 4) Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, secretarial staff, and nurses who care for patients containing diagnostic quantities of radiopharmaceuticals, will not normally be issued dosimeters. If the RSO deems that such personnel must be measured for exposure, a whole body dosimeter will be issued for three months.
- 5) All monthly personnel dosimeter reports will be posted for workers to read. Workers should sign the report when they have read it.

Radiation Safety Committee

The applicant will not establish a Radiation Safety Committee, because no such committee is possible in a private office. The RSO will, however, carry out the activities as established in 10 CFR 35.21, 35.22 and 35.23.

ALARA Program

The applicant will establish an ALARA program as outlined in Appendix G to the Regulatory Guide 10.8, Rev. 21 NRC or an equivalent Agreement State Regulation, excepting the formation of a Radiation Safety Committee. The ALARA concept will be applied on an informal basis by the RSO.

The key elements of this program will be:

- 1) Commitment to keeping individual and collective doses as low as is reasonably achievable.
- 2) An ongoing review of the radiation safety program, with a more formal review performed at least annually.
- 3) Modifications of the radiation safety program, equipment/procedures, if such changes will reduce personnel exposure.
- 4) Establishment of "Investigational Levels" below the applicable limit, as stated in page two of this section.
- 5) Routine reviews by the RSO of the safety program (annually), occupational exposures (quarterly and monthly), and radiation surveys (monthly).
- 6) Cooperation with workers to reduce exposures.
- 7) An educational program for all workers on radiation safety (see the "Training Program.")

Radiation Safety and Quality Control Schedule Table

Radiation Safety Officer and Nuclear Personnel Guide to Activities Required of the Nuclear Medical Facility

	Daily	Weekly	Monthly	Quarterly	6 Months	Annually	Other Frequencies
Survey Instruments							
Battery Check							
Reference Check							
Calibration						•	After Service
Dose Calibrator							
Geometry							Installation/Service
Linearity				•			After service
Gamma Camera							
PHA	•						After service
Resolution							
Uniformity	•						After service
30,000 Cts			•				
Background Flood				•			After service
Interlocks & Switches						•	After service
Area Surveys (Contamination)							
Exposure Survey							
Storage		•					
Sealed Source Leak Testing							
Leak Test							Upon Damage
Sealed Source Inventory				•			Upon Suspected Loss
Worker Instruction							
Initial Instruction						•	Prior to first entry
Personnel Monitoring							
Prior Dose							Prior to first entry
Exposure Reports			•			•	
Accumulated Exposure							Upon termination

Note: This is a guide check your license for specific requirements
 Requirements: Title 10 Parts 19, 20 and 35 of the Federal Code of Regulations and State Requirements

Radiation Officer use

APPLICATION FOR MATERIAL LICENSE

ATTACHMENT 10

The following notices will be posted at the same location as the film badge (whole bod?) reports.

The signs shown are smaller than actual size.

ALARA

(As Low As Reasonably Achievable)

This facility is dedicated to maintaining all exposures to radiation as far below the dose limits as is practically consistent with the purpose for which the licensed activity is undertaken.

If you have any suggestions on how exposures can be reduced, please contact your supervisor or the RSO—Radiation Safety Officer.

NOTICE TO ALL RADIATION WORKERS

This notice should be posted with the personnel dosimetry reports.

Please review the personnel dosimetry information on the dosimeter report. Note any exposure levels that are lower or higher than expected. As a facility committed to maintaining occupational radiation exposure as low as reasonably achievable (ALARA), we have established levels of exposure lower than those mandated by current regulations. Please compare your current levels to those given in the following table.

Acceptable Levels of Radiation Exposure (mRems)

	Level I (10%MPD*) month	Level II (30% Level III) month	Level III (MPD*) month
Whole body, head and trunk, blood forming organs, or gonads	42mR (0.42mSv)	125mR (1.25mSv)	417mR (4.17mSv)
Hands and forearms, feet, and ankles	417mR (4.17mSv)	1,250mR (12.5mSv)	4,166mR (41.7mSv)
Skin of whole body from beta exposure	417mR (4.17mSv)	1,250mR (12.5mSv)	4,166mR (41.7mSv)
Lens of eyes	125mR (1.25mSv)	375mR (3.75mSv)	1,250mR (12.5mSv)

From Title 10, Part 20.1201(e)

After reviewing the report, please initial the report next to your name to indicate your review. Please contact the Radiation Safety Officer (RSO) if you have any suggestions to reduce your exposure. Also contact the RSO if your exposure status has changed or may change. This includes changes in your activities, types of procedures or techniques. Employees wishing to establish a Declared Pregnant Worker Status should contact the RSO.

1000-1012-01-0000-0000

Procedure for Spills

The following procedures for major* and minor* spills will be followed in our facility. These procedures will be posted, in larger form, and used in the employee training program, as indicated in that section.

NOTICE

SPILL PROCEDURE

MINOR SPILLS

1. Notify all persons in the area that a spill has occurred.
2. Prevent the spread of the contamination by covering the spill area with absorbent paper and secure the area.
3. Survey all personnel in the area to assure they are not contaminated. If contamination is present, decontaminate.
4. With the RSO or another person not involved in the spill do the monitoring with the GM survey meter, determine the margins of the contaminated area for decontamination.
5. Clean up the spill using disposable gloves, foot coverings if indicated, and absorbent paper. Remove the paper covering the area, clean side out, avoiding contamination, and place in a plastic bag for transfer to the radioactive waste container. Clean the area, decontaminate, and place all wipes, papers, and gloves in the bag for transfer to the waste container.
6. After decontamination, survey the area with the GM survey meter. Included in the survey the area around the spill area, Check your hands, clothing, and shoes for contamination.
7. Complete the "Radioactive Spill Report" and "Radioactive Spill Contamination Survey."
8. With the RSO, evaluate measures to be taken to prevent such spills.

MAJOR SPILLS

1. Clear the area by notifying all persons in the room that a spill has occurred by use caution that no individual who is contaminated will leave the area.
2. Prevent the spread of the contamination by covering the spill area with absorbent paper and secure the area.
3. Confine the movement of potentially contaminated personnel to an area, in the same room, where they can be monitored and decontaminated. Be sure that they don't spread the contamination. Survey these people and, if not contaminated, have them leave the area.
4. If practical, without spreading the contamination, shield the spill but don't allow the spread of contamination or increase your exposure.
5. Close the room and lock, or otherwise secure the area, to prevent entry. Post a notice on the door indicating that entry is prohibited.
6. Notify the Radiation Safety Officer (RSO).
7. Follow the direction of the RSO for decontamination of the area, complete required documentation and evaluation of the incident.

Personnel Decontamination Suggestions (First Steps):

- a) Remove contaminated clothing and store it for evaluation and decay.
- b) Flush the skin with tepid water, wash with mild soap, and dry with absorbent paper. Repeat this step as required as long as at least 15% of the counts are removed with each washing. Avoid contamination from the wash water and use as little water as practical.
- c) Radioactive material in the eyes should be flushed with water, or eye wash, and an eye cup.

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* The applicant considers a 'major' spill to be a release of more than 50 mCi of ^{99m}Tc , or more than 25 mCi of ^{201}Tl . A major spill may also be defined as one in which a potential exposure rate of more than 10 mrem per hour could occur. Sealed sources, being solid material, cannot spill. If sealed sources could spill, values for a spill considered 'major' would be adjusted upward.

Procedure for Area Surveys

Ambient Exposure Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be surveyed at the end of each day.
- 2) Areas that are used for only radiopharmaceutical waste storage, where there are no daily activities, will be surveyed at the end of each week.
- 3) The above survey information will be recorded on the "Ambient Exposure Survey" report form (see next page), and the RSO will be notified if unexpectedly high (2X normal background) or low levels are found. Prompt notification is particularly important where radionuclides should not be present, or levels exceed established values.
- 4) Surveys will be completed as part of the "spill" procedure.

Removable Contamination Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be wipe tested at the end of each week that the materials are used.
- 2) Areas that are used for only radiopharmaceutical waste storage, where no daily activities take place, will be wipe tested at the end of each week.
- 3) The above survey information will be recorded on the "Contamination Survey Record" report form (see page three). The RSO will be notified if removable contamination greater than 2000 dpm/100cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl is found. Also notify the RSO if 100dpm/100cm² of any other radioisotope is found, or if any removable contamination is found in a unrestricted area. The assay must be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl. The assay must also be able to detect 200 dpm/100cm² of any other radioisotope. This assay will use the absolute counting technique outlined in the "Contamination Survey Record." The survey will use "swipes," as indicated on the third page of this section.
- 4) Removable contamination surveys will be completed as part of the "spill" procedure.

CONTAMINATION ACTION LEVELS: (DPM/100 CM² OF SURFACE CONTAMINATION)

Area	Contaminant Radionuclide
	⁵⁷ Co, ^{99m} Tc, ²⁰¹ Tl
Unrestricted Areas or Uncontrolled Areas	2,000

Decontamination Procedures

I. General Rules

- A. Contain the contamination — never allow uncontaminated areas to be contaminated in the clean-up process.
- B. Avoid any activity release from the restricted area by immediately isolating the suspected area. It is acceptable to "overreact" to the spill by initially isolating an area significantly larger than the initial spill site.
- C. Address personnel contamination before decontaminating the facility.
- D. Obtain others' help to monitor and carry out decontamination procedures and other activities.
- E. Always follow the license conditions and establish protocols for spills, surveys, and documentation.

II. Personnel Decontamination

- A. If physical injury requires medical attention, administer care immediately. Keep in mind that contamination may be present.
- B. Decontaminate eyes by washing them with the eye wash solution from the "Decontamination Kit." Wash eyes over a sink and allow the water to flush down the drain.
- C. Remove all contaminated garments, i.e., laboratory coat, gloves, etc., and step onto an uncontaminated surface to monitor residual activity.
- D. Use the following decontamination techniques for skin decontamination. Take great care not to spread the contamination to clean surfaces during these procedures. Decontaminate in a sink, and allow the water to flush down the drain.
 1. Flush the surface with tepid water, and remonitor for removal/residual activity.
 2. Wash with NUC-WASH I and rinse with tepid water. Remonitor for removal/residual activity.
 3. Wash with NUC-WASH II and NUC-WASH III, if necessary. With each wash, rinse with tepid water and remonitor for removal/residual activity.
 4. If NUC-WASH III is used, and residual activity exists, use a soft brush on the skin. AVOID BREAKING OR IRRITATING THE SKIN.
 5. If residual activity persists after all decontamination steps are completed, and if the RSO agrees that additional decontaminations are not warranted or practical, then ensure that the contaminated area is not further spread and contaminated materials are not ingested. Adding moisture to the skin may allow contaminated skin to release more activity after a few hours. At that time, washing the skin again may be helpful. If hands are contaminated, cotton gloves may absorb moisture containing activity and prevent contamination from spreading.
 6. Determine the value of performing Bio-Assays on the individual for any ingested or inhaled activity. These Bio-Assay techniques include, but are not limited to: nose wipes, saliva samples, and/or after a few hours, blood and/or urine samples. If any Bio-Assay samples are obtained, the personnel exposure records must show the nature of the samples, and the numerical results of their analysis.
 7. Complete all required records, including the appropriate spill, personnel exposure, ingestion, or incident reports.

(continues on Attachment M5B)

Decontamination Procedures (continued from M5A)**III. Surface Decontamination**

- A. Avoid all unnecessary exposure of personnel during decontamination, and never allow uncontaminated areas to become contaminated during these procedures.
- B. Consider using radioactive decay as a decontamination technique if the activity can be isolated and secured.
- C. Wear booties, gloves, a laboratory coat and, if possible, an apron, or other materials that will allow easy removal of contaminated articles.
- D. Cover all "wet" areas with absorbent papers.
- E. Monitor the area suspected of contamination, and identify its outer limits with a marker or barrier.
- F. Place absorbent pads adjacent to the area to prevent exposure to decontamination personnel.
- G. Decontaminate the outer margins of the area with the appropriate NUC CONTAM Solution (A, B, and/or C,) working inward toward the major area of the spill.
 - 1. Use a minimum amount of solution and water.
 - 2. Clean successively smaller areas.
 - 3. Use tongs; don't touch the wipes or decontamination materials.
 - 4. Place all contaminated materials in plastic bags for Decay in Storage (DIS).
 - 5. After decontamination, place absorbent paper over the "clean" area to avoid contact with residual activity.
 - 6. When all areas are decontaminated and released, they must be swipe tested for residual activity.
 - 7. Complete all required spill reports and records and document the decontamination.

Procedure for Ordering Radioactive Materials

We will follow the procedures below when ordering radioactive materials.

1. The RSO or a designee must authorize each order for radioactive materials. Each ordered material must be authorized under the license. The amount ordered must not exceed the possession limits under that license.
2. A record of all orders will be maintained. The record should show the isotope, activity, for and supplier of the radioactive material (see the "Radioactive Material Package Order and Receipt Record.")
3. Radioactive materials will only be received during normal working hours. The materials will be delivered directly to the nuclear medical area and placed on the table by the nuclear medical technologist or RSO, as indicated on the floorplan. If the technologist or RSO are not present when the material is delivered, the reception staff will follow the procedures listed below. The procedures will also be posted in both the reception office and the nuclear medical room.
4. The technologist or RSO will check to ensure that the package contains the ordered material.
5. The technologist or RSO will then follow the "Procedures for Safely Opening Packages Containing Radioactive Material."

NOTICE

Receipt of Packages Containing Radioactive Materials

When Packages containing radioactive materials are delivered, have the carrier agent wait in the reception area and **call** the nuclear technologist or the Radiation Safety Officer.

If the nuclear technologist or the Radiation Safety Officer are not available, then follow **the** following instruction:

1. Have the carrier place the package on a cart or wheelchair.
2. If the package is damaged or shows signs of being wet or having been wet, immediately contact one of the individuals listed below and:
 - Demand that the carrier's agent, the delivery person, remain at the facility to be monitored to determine that neither this person nor the vehicle is contaminated and,
 - Do not touch the package or allow others to touch the package but remove it, on the cart or wheelchair, to a secure area, i.e., the nuclear medicine room, where it will be examined by the RSO or other authorized personnel.
3. If the package is not damaged and shows no signs of being wet:
 - Sign the receipt and retain a copy.
 - Transport the package to the nuclear medicine area on the cart or wheelchair and:
 - Place the package at the location marked: "Radiopharmaceutical Receipt Area." and secure (lock) the room.

Note to cleaning, security, and other personnel: **If** packages should be delivered during non-working hours but while you are present, you are **NOT** authorized to make a receipt, and the package must be refused. The carrier's agent may not leave the package. The package must be refused. The carrier's agent may not leave the package at the facility during non-working hours. If you have any questions, contact the individual listed below:

Radiation Safety Officer: _____

Nuclear Medical Technologist: _____

Procedure for Safely Opening Packages Containing Radioactive Material

Procedure for safely opening packages:

- 1) Wear rubber or latex gloves to prevent hand contamination.
- 2) Visually inspect the package for any sign of damage, such as wetness, physical damage, stains, etc., and if any is noted, immediately notify the RSO.
- 3) Measure the exposure rate from the package with a GM type survey meter (side window) at 1 meter, and then at the surface. If the exposure rate is higher than expected, stop and notify the RSO for specific instructions before proceeding. (Exceptions: See 20.1906)

Note: The maximum surface exposure rate of labeled packages is: White 1-0.5 mR/hr, Yellow 1-50 mR/hr, and Yellow 111-200 mR/hr. None of these rates should be exceeded. (DOT 49 CFR 172)

- 4) Wipe an area of 300 square cm to evaluate the possible presence of removable contamination. Measure wipes using a sodium iodide true detector to insure dpm do not exceed regulatory limit. (See 5f2)
- 5) If the initial surveys are satisfactory, open the package according to the following procedure:
 - a) Remove the packing slip.
 - b) Open the outer package following the supplier's instructions, if instructions are provided.
 - c) Open the inner package and verify that the contents agree with the packing slip.
 - d) Check the integrity of the final source container. Look for broken seals, loss of volume, moisture, or stains on the packing material. If anything is found in a condition other than expected, immediately notify the RSO.
 - e) Remove the source container and place it on an absorbent pad.
 - f) Remove the now empty shipping box to an area with low background exposure, and survey with a sensitive GM survey meter. If the box is contaminated:
 - (1) Treat as radioactive waste and remove for DIS and
 - (2) Wipe the external surface of the final source container and assay the wipe, in a low background area, for any removable radioactivity. Use the procedure for assay of wipes as established in the "Contamination Survey Record" (section III) to determine the sample counts to dpm.
 - (3) Notify the RSO.
 - g) If the shipping box is not contaminated, remove and obliterate the radiation labels before discarding in the in-house trash.
- 6) Recheck the contents of the package to be sure it is the material that was ordered.
- 7) Check the activity of the source in the Dose Calibrator.
- 8) Log the material "in" on the correct Radioisotope Distribution Record.
- 9) Finish the "Radioactive Material Package Order and Receipt Record" as provided on the next page of this section.

DIS — Decay In Storage

dpm — Disintegrations Per Minute

Procedure for Area Surveys

Ambient Exposure Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be surveyed at the end of each day.
- 2) Areas that are used for only radiopharmaceutical waste storage, where there are no daily activities, will be surveyed at the end of each week.
- 3) The above survey information will be recorded on the "Ambient Exposure Survey" report form (see next page), and the RSO will be notified if unexpectedly high (2X normal background) or low levels are found. Prompt notification is particularly important where radionuclides should not be present, or levels exceed established values.
- 4) Surveys will be completed as part of the "spill" procedure.

Removable Contamination Surveys

- 1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be wipe tested at the end of each week that the materials are used.
- 2) Areas that are used for only radiopharmaceutical waste storage, where no daily activities take place, will be wipe tested at the end of each week.
- 3) The above survey information will be recorded on the "Contamination Survey Record" report form (see page three). The RSO will be notified if removable contamination greater than 2000 dpm/100cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl is found. Also notify the RSO if 100dpm/100cm² of any other radioisotope is found, or if any removable contamination is found in an unrestricted area. The assay must be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of ⁵⁷Co, ^{99m}Tc, or ²⁰¹Tl. The assay must also be able to detect 200 dpm/100cm² of any other radioisotope. This assay will use the absolute counting technique outlined in the "Contamination Survey Record." The survey will use "swipes," as indicated on the third page of this section.
- 4) Removable contamination surveys will be completed as part of the "spill" procedure.

CONTAMINATION ACTION LEVELS: (DPM/100 CM² OF SURFACE CONTAMINATION)

Area	Contaminant Radionuclide
	⁵⁷ Co, ^{99m} Tc, ²⁰¹ Tl
Unrestricted Areas or Uncontrolled Areas	2,000

RADIOISOTOPE WASTE DISPOSAL PROCEDURE

Disposal By Transfer

- 1) Spent syringes and unused sources obtained from the radiopharmacy will be returned to the supplier. Or y materials from the radiopharmacy will be returned to the supplier. Retain records of all materials returned to the radiopharmacy with the "Unidose Record—Radiopharmacy Radiopharmaceutical Unidose Record" form, located in the Radiopharmaceutical Record section of this application.

Disposal By Decay-In-Storage (DIS)

- 1) Short-lived material, i.e., materials with a physical half-life of less than 65 days, will be disposed of by DIS
- 2) Radioisotopes that are currently active (activities not used nor returned to the radiopharmacy) will be kept in the lead storage container for not less than two half-lives. These will then be transferred to the DIS storage container, as described below, after the radiation label has been violated and shielding removed.
- 3) Syringes and capped needles will be placed in a separate container for eventual disposal (after DIS), in compliance with state and local public health regulations .
- 4) Injection paraphernalia, such as swabs, gauze, tubes, and other contaminated materials, will be placed directly in the DIS containers.
- 5) All materials placed in the DIS container will have the radiation labels violated and the shielding removed. These materials will be placed inside the container, in 2-ply plastic bags. When the bag is full, or every few weeks, the bag will be sealed with string or tape, and identified with the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The bag will then be contained for additional DIS, if required. No material will be disposed in less than 10 half-lives of the longest half-life in the container.
- 6) Prior to disposal , as in-house waste, the bag will be monitored with the following technique:
 - a) GM survey detector will be checked for proper operation
 - b) Bag will be removed to a low-level background area (less than 0.05 mR/hr)
 - c) All surfaces of the bag will be monitored
 - d) If there is no exposure above background, the bag may be discarded. If there is exposure, the bag will be returned to DIS
 - e) Complete records of DIS will be maintained on the "Disposal By Decay In Storage Record" form, located on the next page

Note: Sealed sources, such as ^{67}Co , ^{132}Ba , and ^{137}Cs , that must be disposed of by the applicant, will be disposed of by transfer to a supplier who has a license to receive such material. This transfer will be completely documented by the applicant prior to disposal.

Personnel External Exposure Monitoring Program

Personnel External Exposure Monitoring Program

Our Personnel Exposure Monitoring Program will include, but not be limited to, the following activities:

- 1) The RSO will promptly review all exposure reports and look for workers whose exposure is unexpectedly high or low.
- 2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body film badge. A contract service will process these badges monthly.
- 3) All individuals who handle radioactive material that emits ionizing photons on a regular basis will be issued a TLD finger monitor. A contract service will process these badges monthly.
- 4) Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, secretarial staff, and nurses who care for patients containing diagnostic quantities of radiopharmaceuticals, will not normally be issued dosimeters. If the RSO deems that such personnel must be measured for exposure, a whole body dosimeter will be issued for three months.
- 5) All monthly personnel dosimeter reports will be posted for workers to read. Workers should sign the report when they have read it.

Radiation Safety Committee

The applicant will not establish a Radiation Safety Committee, because no such committee is possible in a private office. The RSO will, however, carry out the activities as established in 10 CFR 35.21, 35.22 and 35.23.

ALARA Program

The applicant will establish an ALARA program as outlined in Appendix G to the Regulatory Guide 10.8, Rev. 2 NRC or an equivalent Agreement State Regulation, excepting the formation of a Radiation Safety Committee. The ALARA concept will be applied on an informal basis by the RSO.

The key elements of this program will be:

- 1) Commitment to keeping individual and collective doses as low as is reasonably achievable
- 2) An ongoing review of the radiation safety program, with a more formal review performed at least annually.
- 3) Modifications of the radiation safety program, equipment/procedures, if such changes will reduce personnel exposure.
- 4) Establishment of "Investigational Levels" below the applicable limit, as stated in page two of this section.
- 5) Routine reviews by the RSO of the safety program (annually), occupational exposures (quarterly and monthly), and radiation surveys (monthly).
- 6) Cooperation with workers to reduce exposures.
- 7) An educational program for all workers on radiation safety (see the "Training Program.")

Shore Cardiology
Consultants LLC
Application# 29-304-97-01

Attachment #11



CAUTION



RADIOACTIVE MATERIALS

DO NOT EMPTY

RADIOACTIVE WASTE MATERIALS

**RADIOPHARMACEUTICALS
TO BE RETURNED TO THE
RADIOPHARMACY**

RADIOISOTOPE! WASTE DISPOSAL PROCEDURE

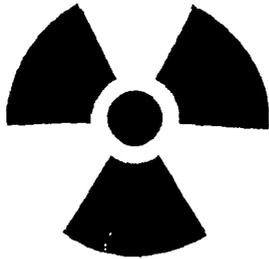
Disposal By Transfer

- 1) Spent syringes and unused sources obtained from the radiopharmacy will be returned to the supplier. *Only* materials from the radiopharmacy will be returned to the supplier. Retain records of all materials returned to the radiopharmacy with the "Unidose Record—Radiopharmacy Radiopharmaceutical Unidose Record" form, located in the Radiopharmaceutical Record section of this application.

Disposal By Decay-In-Storage (DIS)

- 1) Short-lived material, i.e., materials with a physical half-life of less than 65 days, will be disposed of by DIS.
- 2) Radioisotopes that are currently active (activities not used nor returned to the radiopharmacy) will be kept in the lead storage container for not less than two half-lives. These will then be transferred to the DIS storage container, as described below, after the radiation label has been violated and shielding removed.
- 3) Syringes and capped needles will be placed in a separate container for eventual disposal (after DIS), in compliance with state and local public health regulations.
- 4) Injection paraphernalia, such as swabs, gauze, tubes, and other contaminated materials, will be placed directly in the DIS containers.
- 5) All materials placed in the DIS container will have the radiation labels violated and the shielding removed. These materials will be placed inside the container, in 2-ply plastic bags. When the bag is full, or every few weeks, the bag will be sealed with string or tape, and identified with the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The bag will then be contained for additional DIS, if required. No material will be disposed in less than 10 half-lives of the longest half-life in the container.
- 6) Prior to disposal, as in-house waste, the bag will be monitored with the following technique:
 - a) GM survey detector will be checked for proper operation
 - b) Bag will be removed to a low-level background area (less than 0.05 mR/hr)
 - c) All surfaces of the bag will be monitored
 - d) If there is no exposure above background, the bag may be discarded. If there is exposure, the bag will be returned to DIS
 - e) Complete records of DIS will be maintained on the "Disposal By Decay In Storage Record" form, located on the next page

Note: Sealed sources, such as ^{57}Co , ^{133}Ba , and ^{137}Cs , that must be disposed of by the applicant, will be disposed of by transfer to a supplier who has a license to receive such material. This transfer will be completely documented by the applicant prior to disposal.



CAUTION



RADIOACTIVE MATERIALS

DO NOT EMPTY

RADIOACTIVE WASTE MATERIALS

**RADIOPHARMACEUTICALS
TO BE RETURNED TO THE
RADIOPHARMACY**

This is to acknowledge the receipt of your letter/application dated

2/6/2009, and to inform you that the initial processing which includes an administrative review has been performed.

RENEWAL 29-30497-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143418
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader